



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/539,765

02/08/2006

Michael Grant

1662.004US2

2018

45836

7590

02/18/2009

SCHWEGMAN, LUNDBERG & WOESSNER/NIH

PO BOX 2938

MINNEAPOLIS, MN 55402-0938

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

02/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,765	Applicant(s) GRANT, MICHAEL	
	Examiner Kailash C. Srivastava	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 8-63 is/are pending in the application.
- 4a) Of the above claim(s) 11, 18, 19, 21, 22, 29, 30, 34, 35, 41-61, 63 and 3739 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-10, 12-17, 20, 23-28, 31-33, 36, 40 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/28/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The response, amendment and remarks filed 28 October 2008 to the Office Action mailed 28 July 2008 is acknowledged and entered.

General Informal Matters

2. This application contains claims 11, 18-19, 21-22, 29-30, 34-35, 37-39, 41-61 and 63 drawn to a non-elected invention with traverse in the reply filed on 17 April 2008. A complete reply to the instant final rejection must include cancellation of nonelected claims or other appropriate action (37 C.F.R. §1.144) See M.P.E.P. §821.01.

Withdrawn Rejections

3. In view of amendments to the Claims , specifically Claim 1, wherein at Line 3, the phrase “pathogenic Escherichia coli has been added, but the phrase “target microbes” has been deleted and at line 5 abridging Line 6, the phrase “non-pathogenic or” has been deleted, the obviousness rejection of Claims 1-10, 12-17, 20, 23-28, 31-33, 36 and 40 under 35 U.S.C. § 103 (a) as obvious over combined teachings from Feldsine et al. (U.S. Patent 6,379,918) in view of Bochner (U.S. Patent 6,136,554) is hereby withdrawn,

Claims Status

4. Claims 5-7 have currently been cancelled.
5. Claims 62-63 have currently been added.
6. Claims 1-4, and 8- 63 are currently pending.
7. Claims 11, 18-19, 21-22, 29-30, 34-35, 37-39, 41-61 and 63 remain withdrawn.
8. Claims 1-2, 8 and 31-33 have currently been amended.
9. Claims 1-4, 8-10, 12-17, 20, 23-28, 31-33, 36-40 and newly presented Claim 62 are currently under examination on merits

Information Disclosure Statement

10. Information Disclosure Statement (i.e., IDS) filed 28 October 2008 is acknowledged, made of record, considered and duly initialed USPTO Form 1449 or equivalent is enclosed with the instant Office Action.

Claim Rejections - 35 U.S.C. § 103

11. In view of the amendments filed 28 October 2008, following is a new rejection to Claims 1-10, 12-17, 20, 23-28, 31-33, 36 and 40 under 35 U.S.C. § 103 (a).

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-10, 12-17, 20, 23-28, 31-33, 36 and 40 and the newly presented Claim 62 are rejected under 35 U.S.C. § 103 (a) as obvious over combined teachings from Hovde et al (1999. Effect of Cattle Diet on *Escherichia coli* O157:H7 Acid Resistance, Applied And Environmental Microbiology, Volume Vol. 65, No. 7, Pages 3233–3235) in view of Stancik et al (2002. pH-Dependent Expression of Periplasmic Proteins and Amino Acid Catabolism in *Escherichia coli*. Journal Of Bacteriology, Volume. 184, No. 15, Pages 4246–4258) and further in view of Lan et al (Microbes and Infection, Volume 4, Number 11, Pages 1125-1132, Applicants IDS submitted 10/28/2008).

Claims recite a method to segregate pathogenic and non-pathogenic microbes and to enrich and detect a target pathogenic enterohemorrhagic, enteropathogenic or enterotoxigenic microorganism via incubating sample in an acidic medium at a pH between 2-4 and in temperature ranging from about 5 °C to about 35 °C in presence of a selective medium.

Hovde et al., teach enrichment of *Escherichia coli* by suspending fecal samples comprising *Escherichia coli* (i.e., *E. coli*) O157:H7 in Trypticase soy broth, pH 2.0, incubated 1 h at 37°C, and neutralized by dilution. Bacteria were enumerated by plate count. Although there was variation in *E. coli* O157:H7 percent survival among the isolates obtained from the animals, there was consistently less than 1 log of *E. coli* O157:H7 death, and the difference between these two groups was insignificant at $P=0.77$ (Page 3232, Column 2, Line 56 to Page 3233, column 1, Line 3 under Figure 1; (Table 1). Note

Trypticase soy broth is TSB. Hovde et al., however, are silent regarding the selective pressure of pH in range of 1-6, sorbitol as well as shiga toxin producing *E. coli* O157:H7. Stancik et al., teach *E. coli* growing in pH range of 4...4-9.2 and Lan et al., teach growth of *E. coli* in the presence of sorbitol (Table 1) and shiga-like toxin (Table).

A person of ordinary skill in the art at the time the invention was made would be motivated to combine teachings from Havde et al., according to the teachings From each one of Stancik et al., and Lan et al., to obtain a method to selectively isolate and distinguish enterohemorrhagic *Escherichia coli* O157:H7 isolates; because Stancik et al., clearly teach different pH to grow *Escherichia coli* and Lan et al., show growth of *E. coli* in presence of sorbitol as well as shiga toxin producing *E.coli*.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Havde et al., according to the teachings From each one of Stancik et al., and Lan et al., to obtain a method to selectively isolate and distinguish enterohemorrhagic *Escherichia coli* O157:H7 isolates; because Stancik et al., clearly teach different pH to grow *Escherichia coli* and Lan et al., show growth of *E. coli* in presence of sorbitol as well as shiga toxin producing *E.coli*.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the Contrary.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. For the aforementioned reasons, no claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kailash C Srivastava/
Examiner, Art Unit 1657

Kailash C. Srivastava
Patent Examiner
Art Unit 1657
(571) 272-0923
16 February 2009
/David M. Naff/
Primary Examiner, Art Unit 1657